

Remarks

Claims 1-2, 4-20, and 22-39 are presented for the Examiner's review and consideration. Herein, claim 13 has been amended. Applicant believes the claim amendments and the accompanying remarks, herein, serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §102(b) Rejection

Claims 1-2, 4-20, and 22-39 were rejected under 35 U.S.C. §102(b) as being anticipated by Matsen, III et al. (4,979,949) ("Matsen"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

The invention has been discussed in a previous response, and in the interest of brevity, that discussion is incorporated by reference, herein.

Matsen discloses positioning a tool relative to a patient's bone to facilitate the performance of a surgical bone alteration task. (Abstract). The system comprises a bone immobilization device for supporting the bone in a fixed position with respect to a reference structure, and a robot that includes a base fixed in position with respect to the reference structure. (Id).

With reference to Fig. 19 thereof, it can be seen that Matsen discloses a robotically held cutting guide. As can further be seen in the figures, it is not intended that the guide contacts the bone. Specifically, "One robot safety feature that is available using the bone alteration program is the concept of a 'safe sphere.' This is an area of a previously defined dimension that surrounds the learned position of the bone. The robot will only enter the sphere if it is commanded to do so, and will move within the sphere only along a straight line; i.e., toward the line corresponding to the approach edge that is defined for each cut and bore defined in the geometric database. When retreating from the safe sphere, the robot will retreat along the same line. Rotational and translational motion of the tool takes place only outside of the safe sphere, thereby *protecting the femur and exposed knee from damage caused by inadvertent touching or striking by the tool.*" (Col. 23, lns. 15-28).

As further stated in Matsen, “The top and bottom plates are made of a rigid material, preferably stainless steel or other material that is suitable for use in the surgical environment. The liners 238 are preferably made of a low-friction material, such as Teflon. In one embodiment, the liners are permanently bonded to the plates by epoxy. Alternatively, the liners are provided with a strip of adhesive 244 to attach them to the plates. The latter guide liners are preferably disposable to avoid the need to resterilize them as well as to avoid wearing of the liners which may result in residue from the liners falling into the exposed area. By using adhesive strips 244, the liners can be easily attached and removed from the plates.” (Col. 25, lns. 1-13).

The rejection states that Matsen discloses “a disposable cutting guide fabricated from a polymeric material and designed for a single use”. However, as can be seen in the preceding quote, the guide is preferably made of stainless steel, an expensive material that would not be considered disposable within the relevant art. The Teflon liner of Matsen is inserted within the non-polymeric guide, and, of course, the liner does not meet the elements of a cutting guide, as claimed.

The rejection does not address the element of claim 1, that the cutting guide is *positioned through the expanded incision and on a surface of a distal end portion of the femur*. Not only does Matsen directly state and show that the tool should not contact the bone, but indeed the guide of Matsen does not work by being oriented on the bone.

Also not addressed is the element, again missing in Matsen, of *moving a cutting tool through the incision into engagement with a guide surface on the cutting guide*. As the guide of Matsen is not passed through the bone, it does not present a guide surface after having passed through the incision.

Further not addressed is the element in claim 1 of a *cutting guide sized to be received in the expanded incision*. It is clear from Fig's. 19 and 20 (containing the references 215, 238 cited in the rejection) that the guide of Matsen is substantially larger than the bone to be cut. The guide of Matsen could not be inserted within an expanded incision, since it is wider than the knee, nor is it intended to be inserted within an expanded incision.

Arguments made with respect to claim 1 apply equally to claim 19.

In the “Response to Amendment” section of the Office Action, it is pointed out that a disposable guide cannot also be “readily modified in successive iterations”. Applicant has amended claim 13 to specifically recite “wherein the design of said cutting guide, the cutting guide being both polymeric and disposable, is readily modified in successive iterations for new or customized instrumentation”. Clearly, Matsen does not disclose or suggest modifying the design of a polymeric, disposable cutting guide for new or customized instrumentation, and thus cannot anticipate claim 13 as amended.

Accordingly, Applicant respectfully submits that independent claims 1, 13, and 19 are patentable over Matsen. As claims 2, 4-12, 31-33 and 38 depend from claim 1; claims 14-18, 34 and 39 depend from claim 13; and claims 20, 22-30 and 35-37 depend from claim 19, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the remaining dependent claims are allowable over Matsen at least for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of this section 102 rejection.

Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Fees of \$120 for a one month extension, and \$810 for an RCE, are believed to be due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A03-012C).

Respectfully submitted,

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